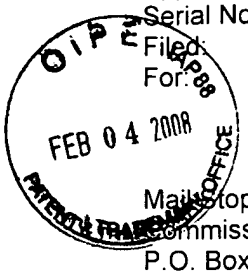
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Thompson et al. Group No.: 9345.17121-CON 1
Serial No.: 09/883,089 Examiner: R. Smith
Filed: 15 June 2001
For: Systems for Applying Ultrasound Energy to the Thoracic Cavity



Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF APPEAL BRIEF
(PATENT APPLICATION 37 CFR 192)

1. Transmitted herewith in triplicate is the APPEAL BRIEF in this application with respect to the Notice of Appeal filed on 30 July 2007 .

NOTE: "THE APPELLANT SHALL, WITHIN 2 MONTHS FROM THE DATE OF THE NOTICE OF APPEAL UNDER S 1.191 IN AN APPLICATION, REISSUE APPLICATION, OR PATENT UNDER REEXAMINATION, OR WITHIN THE TIME ALLOWED FOR RESPONSE TO THE ACTION APPEALED FROM, IF SUCH TIME IS LATER, FILE A BRIEF IN TRIPLICATE." 37 CFR 1.192(A) [EMPHASIS ADDED].

2. STATUS OF APPLICANT
This application is on behalf of
[ ] other than a small entity
[x] small entity

3. FEE FOR FILING APPEAL BRIEF
Pursuant to 37 CFR 1.17(f) the fee for filing the Appeal Brief is:

[x]	small entity	$255.00
[ ]	other than a small entity	$510.00

Appeal Brief fee due $255.00 .

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail with sufficient postage, in an envelope addressed as follows: Mail Stop Appeal Brief - Patents, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

Date 30 January 2008

[Signature of Person Mailing Paper]

Judith Dunaway
[Typed Name of Person Mailing Paper]

4. EXTENSION OF TERM

NOTE: THE TIME PERIODS SET FORTH IN 37 CFR 1.192(A) ARE SUBJECT TO THE PROVISION OF S 1.136 FOR PATENT APPLICATIONS. 37 CFR 1.191(D). ALSO SEE NOTICE OF NOVEMBER 5, 1985 (1060 O.G. 27).

The proceedings herein are for a patent application and the provisions of 37 CFR 1.136 apply.

(complete (a) or (b) as applicable)

(a) [x] Applicant petitions for an extension of time under 37 CFR 1.136 (fees: 37 CFR 1.17(a)(1) - (a)(5)) for the total number of months checked below:

	Extension (months)	Fee for other than small entity	Fee for small entity
[ ]	one month	$ 120.00	$ 60.00
[ ]	two months	$ 460.00	$230.00
[ ]	three months	$1050.00	$525.00
[x]	four months	$1640.00	$820.00

Fee $ 820.00

If an additional extension of time is required, please consider this a petition therefor.

(check and complete the next item, if applicable)

[ ] An extension for _____ months has already been secured and the fee paid therefor of $_____ is deducted from the total fee due for the total months of extension now requested.
Extension fee due with this request _____.

or

(b) [ ] Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

5. TOTAL FEE DUE

The total fee due is:

Appeal brief fee $255.00 _____.

Extension fee (if any) $820.00 ___.

TOTAL FEE DUE $1075.00 ____.

6. FEE PAYMENT

[ ] Attached is a check in the sum of $_____.

[ ] Charge Account No._____ the sum of $_____.

A duplicate of this transmittal is attached.

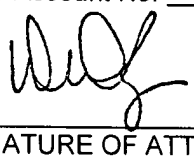
7. FEE DEFICIENCY

NOTE: IF THERE IS A FEE DEFICIENCY AND THERE IS NO AUTHORIZATION TO CHARGE AN ACCOUNT, ADDITIONAL FEES ARE NECESSARY TO COVER THE ADDITIONAL TIME CONSUMED IN MAKING UP THE ORIGINAL DEFICIENCY. IF THE MAXIMUM, SIX-MONTH PERIOD HAS EXPIRED BEFORE THE DEFICIENCY IS NOTED AND CORRECTED, THE APPLICATION IS HELD ABANDONED. IN THOSE INSTANCES WHERE AUTHORIZATION TO CHARGE IS INCLUDED, PROCESSING DELAYS ARE ENCOUNTERED IN RETURNING THE PAPERS TO THE PTO FINANCE BRANCH IN ORDER TO APPLY THESE CHARGES PRIOR TO ACTION ON THE CASES. AUTHORIZATION TO CHANGE THE DEPOSIT ACCOUNT FOR ANY FEE DEFICIENCY SHOULD BE CHECKED. SEE THE NOTICE OF APRIL 7, 1986, 1065 O.G. 31-33.

[x] If any additional extension and/or fee is required, this is a request therefor and to charge Account No. 06-2360.

AND/OR

[x] If any additional fee for claims is required, charge Account No. 06-2360.



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Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Thompson et al.	Attorney Docket No.	9345.17121-CON 1
Serial No.:	09/883,089	Examiner:	Ruth S. Smith
Filed:	15 June 2001	Group Art Unit:	3737
Title:	Systems for Applying Ultrasound Energy to the Thoracic Cavity		

APPEAL BRIEF
TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

APPEAL BRIEF

This Appeal Brief is comprised of the following sections:

(i.) REAL PARTY IN INTEREST

The real party in interest in this case is the assignee, TIMI 3 Systems, Inc., a California corporation doing business at 3032 Coronado Drive, Santa Clara, CA 95054.

(ii.) RELATED APPEALS AND INTERFERENCES

There are no related appeals and/or interferences of which the Applicant's attorney is aware at this time. A notice of appeal was filed on a related case, Serial No. 10/034,833, however this appeal will be abandoned.

(iii.) STATUS OF CLAIMS

Claims 1 to 4, 7 to 12, 14, and 15 remain in the application. Claims 1 to 4, 7 to 12, 14, and 15 are subject to this appeal.

(iv.) STATUS OF AMENDMENTS

The claims presently submitted are the claims as amended in Amendment E, filed at the same time as this appeal brief.

(v.) SUMMARY OF CLAIMED SUBJECT MATTER

Currently there is one independent claim presented, claim 1. Claim 1 refers to an ultrasound applicator with a stabilization assembly, which is most specifically depicted in Figures 4, 5, and 8 as reference numerals 18 and 12, respectively, and described most specifically in the specification at page 7, lines 4-22 and page 9, line 5 through page 10 line 5.

The present invention relates to an ultrasound applicator and, more specifically, to an ultrasound applicator for enhancing blood perfusion. *See*, Specification, page 5, lines 5-8. It has been found that application of ultrasound may be have many therapeutic benefits. *See*, Specification, page 1, lines 18-19. Application of high power, low frequency ultrasound on a blood clot may cause it to break apart and dissolve. *See*, Specification, page 1, lines 21-23. Application of ultrasound to a patient has also been found to increase blood perfusion. *See*, Specification, page 1, lines 26-27. Application of low frequency ultrasound in the presence of a thrombolytic agent has also been found to assist in the breakdown or dissolution of thrombi. *See*, Specification, page 1, lines 23-26. Ultrasound application devices are generally designed to be used by trained medical personnel in a non-mobile environment where electrical service is always available. *See*, Specification, page 1, lines

30-35. However, most patients experience the effects of impaired blood perfusion suddenly and in public and private settings. *See*, Specification, page 1, lines 36-37. These patients need to be transported from the pubic or private setting to a medical facility before treatment can begin. *See*, Specification, page 1, lines 37-40. Critical treatment time may be lost during the time it takes to transport the patient to the medical facility. *See*, Specification, page 1, line 40 to page 2, line 2.

The present invention is a mobile ultrasound applicator with a stabilization device. The ultrasound applicator may be placed on a person's chest, overlaying the sternum, to direct ultrasonic energy toward the vasculature of the heart. *See* Specification, page 4, lines 26-30. The ultrasound applicator includes a housing and at least one ultrasound transducer within the housing. *See*, Specification, page 7, 18-22. The ultrasound applicator also includes a stabilization assembly to position and secure the ultrasound applicator to the patient quickly and accurately even in cramped quarters or in transit. *See*, Specification, page 9, lines 8-12. The compact size of the ultrasound applicator, along with the configuration of the stabilization assembly allows additional treatment devices to be placed on the chest at the same time the ultrasound applicator is being used. *See*, Specification, page 9, lines 27-31.

The ultrasound applicator 18 of the present invention includes a housing 38 which houses at least one transducer. *See* Specification, page 7, lines 20-22. The housing is a metal or plastic body ergonomically sized to be comfortably grasped and manipulated in one hand. *See* Specification, page 7, lines 18-20.

As stated above, the ultrasound applicator includes at least one transducer. The transducer is sized and configured to provide a maximum power density equal to or less than W/cm^2 at a maximum total power output of equal to or less than 200 W operating at a fundamental frequency of less than or equal to 500 kHz. *See* Specification, page 15, lines 7-11. The particular treatment parameters may be chosen based on the outcome desired, and may remain constant throughout the treatment session or may vary throughout the treatment session. *See*, Specification, page 14, lines 18-21.

The present invention includes a stabilization assembly, such as those shown in Figures 4 and 5. The embodiment shown in Figure 4 comprises a sling (62) worn on the back of the patient between the waist and the shoulders. The sling carries a shoulder loop (64) and a waist loop (66), each of the loops may be coupled to the housing of the ultrasound applicator. The embodiment shown in Figure 5 comprises halter straps (70 and 72) worn about the chest and shoulders of the patient. The halter straps are coupled to the housing of the ultrasound applicator.

As is seen in Figures 4 and 5, in either embodiment of the stabilization assembly 12 the configuration of the stabilization assembly 12 leaves the portions of the chest on the lateral sides of the ultrasound applicator 18 bare. "[T]he stabilization assembly 12 preferably occupies only a relatively small area on the chest. *See* Specification, page 9, lines 26-27. In this manner, additional testing, monitoring, or treatment devices may be used on the patient without removing the ultrasound applicator. *See* Specification, page 9, lines 27-31.

Identification of "Means" Terms

Applicant has not used any "means" terms in the claims.

(vi.) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following grounds of rejections are presented for review. This issue is addressed in response to the Office Action of 2 February 2007:

Whether claims 1-4, 7-12, 14 and 15 are unpatentable under 35 U.S.C. § 103(a) over Talish et al, U.S. Pat. No. 6,431,070 in view of Peterson et al, U.S. Pat. No. 6,126,619.

Grouping of the Claims

Claims 1-4, 7-12, 14, and 15 stand and fall together. Included in these claims is the single independent claim 1 from which the remaining claims depend.

(vii.) ARGUMENT

CLAIMS 1-4, 7-12, 14, AND 15 ARE NOT OBVIOUS OVER TALISH ET AL IN VIEW OF PETERSON ET AL

Claims 1-4, 7-12, 14, and 15 stand rejected under 35 U.S.C. § 103(a) over Talish et al., U.S. Pat. No. 6,432,070 in view of Peterson et al., U.S. Pat. No. 6,126,619.

As will be noted, Talish et al. and Peterson et al. lead away from the present invention, do not teach at least one of the claimed features of the present invention, and it would not be an obvious design choice to modify them to arrive at the present invention.

Specifically, claim 1 recites:

> An ultrasound applicator for applying ultrasound energy to the thoracic cavity of an individual, said ultrasound applicator comprising
>
> a housing sized and configured for placement during use on a chest or near a sternum, the housing having inferior and superior edge portions and lateral side portions,

an ultrasound transducer carried within the housing to transcutaneously apply ultrasound energy to the thoracic cavity, the ultrasound transducer being sized to provide a power density not exceeding 3 watts/cm^2 at a maximum total power output of no greater than 200 watts operating at a fundamental therapeutic frequency not exceeding 500 kHz, whereby the application of ultrasound energy increases the blood flow of the individual; and

a strap assembly affixed to inferior and/or superior edge portions of the housing to stabilize the housing during application of ultrasound energy, the strap assembly being substantially free of components affixed to the lateral side portions of the housing, **to leave the chest of the individual on the lateral side portions of the housing substantially uncovered and bare to allow placement of another device on bare skin alongside the housing during use.**
(emphasis added)

Neither Talish et al. nor Peterson et al. teaches leaving the chest of the individual on the lateral side portions of the housing substantially uncovered and bare to allow placement of another device on bare skin alongside the housing during use. The Examiner suggests that if the device shown in Figure 1 of Talish et al were to be placed upon a very large patient, on the lateral side portions of the housing, would be uncovered and bare. The Examiner opines that such a modification would have been an obvious design choice.

Talish et al. states that "[i]n operation, the placement module 14 is positioned and secured to the patient's body as shown by FIG. 2, such that the transducer assembly 16 lies over the pain receptors of the sympathetic nervous system in the injured part of the body." *See* Talish et al., column 5, lines 53-55. A review of Fig. 2 shows the placement module extending across the entire upper chest of the patient. "The placement module 14 is comprised of placement bands 20 and placement support 22." *See* Talish et al., column 5, lines 32-34. Talish et al further states that "[t]he placement support 22 may be construed of hard plastics which may be custom molded for a particular patient." *See* Talish et al., column 5, lines 40-42. Patient comfort is also important to Talish et al., who teach use of a sponge-like material "providing comfort to the patient." *See* Talish et al., column 5, lines 38-40

As taught by Talish et al., the positioning and placement of the placement module on the patient's body is very important. Talish et al. teaches custom molding the placement support of the placement module for a particular patient in order to achieve the appropriate and comfortable placement. Based on the teachings of Talish et al., to treat a very large patient, a very large placement support would be created. In fact, Talish et al. teaches a placement module that extends

across the entire span of the chest of a patient. Talish et al. therefore teaches away from providing a treatment device that leaves the side portions of the chest bare.

It should be noted, the application of the device taught in Talish et al. is for a pain relief treatment. The treatment device is not designed to be used in an emergency setting where a "one size fits all" application device would be desirable. Rather, the treatment device taught in Talish et al. would be custom built for each patient prior to treatment. There is nothing in Talish that teaches or suggests the need to place another device on the bare skin alongside the ultrasound applicator. In fact, because the device taught in Talish et al. is not designed for an emergency setting, there would be no motivation to the side portions of the chest bare to accommodate placement of additional treatment device.

It is true that Talish et al. does contemplate various modifications. However, the modifications suggested by the Examiner, to provide a placement device which leaves the chest bare of the lateral sides, would render Talish's placement device too small to be fitted and placed in the preferred way to work for its intended purpose. There is nothing in Talish et al. to suggest such a modification.

Conclusion

The Examiner currently seeks to deny patentability in this case on the prior art teachings of Talish et al and Peterson et al. None of these patents present or suggest the teachings or combinations of the present invention. The claims succinctly claim what the Applicant believes to patentably distinguish the present invention from the prior art. Neither Talish et al nor Peterson et al teach leaving the chest of the individual on the lateral side portions of the housing substantially uncovered and bare to allow placement of another device on bare skin alongside the housing during use. Further, neither Talish et al nor Peterson et al contemplate a usage where it would be desirable to provide other treatment devices, so there would be no reason to provide bare skin alongside the housing. It would not have been an obvious an obvious design modification to size the placement device of Talish et al. such that the lateral sides of the chest remain bare.

Included is the necessary appeal fee. If any additional fees are required, this is a request to charge Deposit Account No. 06-2360.

(viii.) CLAIMS APPENDIX

Presentation of Claims as Currently Presented, as Amended in Amendment E Filed After Final Rejection

1 (Previously Presented). An ultrasound applicator for applying ultrasound energy to the thoracic cavity of an individual, said ultrasound applicator comprising

a housing sized and configured for placement during use on a chest or near a sternum, the housing having inferior and superior edge portions and lateral side portions,

an ultrasound transducer carried within the housing to transcutaneously apply ultrasound energy to the thoracic cavity, the ultrasound transducer being sized to provide a power density not exceeding 3 watts/cm^2 at a maximum total power output of no greater than 200 watts operating at a fundamental therapeutic frequency not exceeding 500 kHz, whereby the application of ultrasound energy increases the blood flow of the individual; and

a strap assembly affixed to inferior and/or superior edge portions of the housing to stabilize the housing during application of ultrasound energy, the strap assembly being substantially free of components affixed to the lateral side portions of the housing, to leave the chest of the individual on the lateral side portions of the housing substantially uncovered and bare to allow placement of another device on bare skin alongside the housing during use.

2 (Previously Presented). An applicator according to claim 1

wherein the strap assembly includes a quick release mechanism.

3 (Previously Presented). An applicator according to claim 1

wherein the strap assembly includes a quick release material.

4 (Previously Presented). An applicator according to claim 1

wherein the strap assembly includes a sling.

5 (Canceled).

6 (Canceled).

7 (Original). An applicator according to claim 1

wherein the housing includes a chamber to hold fluid about the ultrasound transducer.

8 (Original). An applicator according to claim 1

wherein the housing accommodates circulation of fluid about the ultrasound transducer.

9 (Original). An applicator according to claim 1

wherein the housing includes an ultrasound conducting interface.

10 (Original). An applicator according to claim 1

wherein the housing includes a contour-conforming interface with skin.

11 (Original). An applicator according to claim 1

wherein the housing includes a skirt that spaces the ultrasound transducer from contact with skin.

12 (Original). An applicator according to claim 1

wherein the housing includes an ultrasound-conducting membrane for contacting skin.

13 (Canceled).

14 (Original). An applicator according to claim 1

wherein the housing includes a coupling assembly to releasably couple the ultrasound transducer to an external electric signal generating machine.

15 (Previously presented). An applicator according to claim 14

wherein the assembly includes a quick coupling mechanism.

16 (Canceled).

(ix.) EVIDENCE APPENDIX

1. U.S. Patent No. 6,432,070-Talish et al.
2. U.S. Patent No. 6,126,619-Peterson et al.

(x.) RELATED PROCEEDINGS APPENDIX

(NONE)

Respectfully Submitted,

By_____
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